Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparison of the therapeutic efficacy of pregabalin and duloxetine in peripheral neuropathy induced by taxanes containing chemotherapy regimens in women with breast cancer, a randomized clinical trial.

Protocol summary

Summary

This study is a randomized, double-blind, single-center, phase II clinical trial in Tuba Clinic of Sari. 82 eligible patients were 18 years or older, had at least grade 1 sensory pain based on the NCI Common Terminology Criteria for Adverse Events grading scale and reported 4 on a 10-point scale, average neuropathic pain. Participants with other clinical conditions that cause neuropathies, such as diabetes or trauma, alcohol abuse, central nervous system diseases, heart, hepatic and renal failure, glaucoma, depression, anxiety, bipolar, psychotic disorders, suicidal ideation, receiving other neurotoxic chemotherapy drugs, having concomitant use of MAOI, BZD, gabapentin and females during pregnancy or lactation were ineligible. This study will be blinded for patients and researchers. Patients in duloxetine group, will received 30 mg/day orally for the first week and 30 mg BD for the next for 6 weeks. Patients in pregabalin group, will received 75 mg/day orally for the first week and 75 mg BD (max: 75 mg TDS) for the next for 6 weeks. Sensory neuropathy , severity of pain and quality of life at base line and 3,6 weeks after intervention, will be assessed according to the NCI-CTCAE, VAS and EORTC QLQ-C30 (version 3) respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602112027N5**
Registration date: **2016-07-13, 1395/04/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-13, 1395/04/23

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic efficacy of pregabalin and duloxetine in peripheral neuropathy induced by taxanes containing chemotherapy regimens in women with breast cancer, a randomized clinical trial.

Public title

The therapeutic effects of pregabalin and duloxetine in the treatment of nerve pain caused by certain chemotherapy drugs

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of more than 18 y; NCI Common Terminology Criteria for Adverse Events scale (NCI grade> 1); Minimum rating of NRS scale: 4 (0-10)
Exclusion criteria: Having other clinical conditions that cause neuropathies, such as diabetes or trauma; Alcohol abuse; History of central nervous system diseases; History of heart, hepatic and renal failure (creatinine clearance below 60ml/min); History of glaucoma; History of depression, anxiety, bipolar, psychotic disorders and suicidal ideation; Receiving other neurotoxic chemotherapy drugs; Having concomitant use of MAOI, BZD and gabapentin; Females during pregnancy or lactation; Patients who have received pregabalin or duloxetine in recent 15 days; Having concomitant use of analgesics or effective on nerve activity drugs such as vitamin B12, lamotrigine, valproate and TCA (except pregabalin or duloxetine) will be excluded if they spent a total of 7 days washout, the patients also can be studied; Concomitant use of selected analgesics was allowed (eg, nonsteroidal anti-inflammatory drugs , acetaminophen, aspirin,..) but only patients receiving stable doses in the 2 weeks before randomization could participate: (1) no new analgesics were added, (2) no analgesics were discontinued and (3) the weekly 24-hour total analgesic dose did not fluctuate up or down by more than 10% in the 2weeks before study registration

Age

From **18 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences, Faculty of Pharmacy

Street address

Faculty of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd, Khazar square, Sari, Mazandaran Province

City

Sari

Postal code

861-48175

Approval date

2016-01-26, 1394/11/06

Ethics committee reference number

IR.MAZUMS.REC.94-1897

Health conditions studied

1

Description of health condition studied

Chemotherapy induced peripheral neuropathy

ICD-10 code

62.2

ICD-10 code description

Polyneuropathy due to other toxic agents

Primary outcomes

1

Description

Sensory neuropathy

Timepoint

Before intervention, three weeks after intervention and six weeks after intervention

Method of measurement

According to the NCI Common Terminology Criteria for Adverse Events grading scale

2

Description

Neuropathic pain

Timepoint

Before intervention, three weeks after intervention and six weeks after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention, three weeks after intervention and six weeks after intervention

Method of measurement

EORTC QLQ-C30 (Version 3) questionnaire

2

Description

Side effects

Timepoint

Three weeks after intervention and six weeks after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group 1: Pregabalin 75 mg/day orally for the first week and 75 mg BD (max: 75 mg TDS) for the next for 6 weeks

Category

Treatment - Drugs

2

Description

Intervention group 2: Duloxetine 30 mg/day orally for the first week and 30 mg BD for the next for 6 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tuba Clinic of Mazandaran University of Medical Sciences

Full name of responsible person

Avan Razieh

Street address

Tuba Clinic of Mazandaran University of Medical Sciences, Khazar Blvd, Sari, Mazandaran Province

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Enayati Ahmad ali

Street address

Vice chancellor for research, Moalem square, Sari

City

Sari

Grant name

Grant code / Reference number

30303

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences, Faculty of Pharmacy

Full name of responsible person

Salehifar Ebrahim

Position

Board Certified Clinical Pharmacist, Professor of Clinical Pharmacy

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty